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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary

Application No. **09/866.582**

Applicant(s)

Witman et al

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication. · If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X Responsive to communication(s) filed on *Dec 10, 2002* 2a) This action is **FINAL**. 2b) X This action is non-final. 3)
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 1-36 is/are pending in the application. 4a) Of the above, claim(s) ______ is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) Claim(s) ______ is/are rejected. 7) Claim(s) is/are objected to. 8) X Claims 1-36 are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) ☐ The proposed drawing correction filed on ______ is: a) ☐ approved b) ☐ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) Other:

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DETAILED ACTION

1. An error on the part of the examiner improperly grouped claims 18-23 with the nucleic acid. A new restriction is set forth properly grouping these claims with the appropriate group. The examiner apologizes for this oversight.

Election/Restriction

- 2. Prior to setting forth the restriction requirement, it is noted out that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the method and products rely upon polypeptides, polynucleotides and antibodies which are encoded by different genes and are from different species to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.
- 3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- 1. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 20, classified in class 536, subclass 23.1.
- 2. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 20, classified in class 530, subclass 300.
- 3. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 20, classified in class 530, subclass 388.1.
- 4. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 27, classified in class 536, subclass 23.1.
- 5. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 27, classified in class 530, subclass 300.
- 6. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 27, classified in class 530, subclass 388.1.
- 7. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 46, classified in class 536, subclass 23.1.
- 8. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 46, classified in class 530, subclass 300.
- 9. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 46, classified in class 530, subclass 388.1.
- 10. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 52, classified in class 536, subclass 23.1.
- Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 52, classified in class 530, subclass 300.
- 12. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 52, classified in class 530, subclass 388.1.

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- 13. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 57, classified in class 536, subclass 23.1.
- 14. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 57, classified in class 530, subclass 300.
- 15. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 57, classified in class 530, subclass 388.1.
- 16. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 72, classified in class 536, subclass 23.1.
- 17. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 72, classified in class 530, subclass 300.
- 18. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 72, classified in class 530, subclass 388.1.
- 19. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 88, classified in class 536, subclass 23.1.
- 20. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 88, classified in class 530, subclass 300.
- 21. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 88, classified in class 530, subclass 388.1.
- 22. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 122, classified in class 536, subclass 23.1.
- 23. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 122, classified in class 530, subclass 300.
- 24. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 122, classified in class 530, subclass 388.1.

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25. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 139, classified in class 536, subclass 23.1.

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- 26. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 139, classified in class 530, subclass 300.
- 27. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 139, classified in class 530, subclass 388.1.
- 28. Claims 1-7, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene Che-2, classified in class 536, subclass 23.1.
- 29. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene Che-2, classified in class 530, subclass 300.
- 30. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene Che-2, classified in class 530, subclass 388.1.
- 31. Claims 1-7, drawn to nucleic acids vectors and host cells of murine particle protein gene 57, classified in class 536, subclass 23.1.
- 32. Claims 8, 9, and 16, drawn to murine particle protein gene 57, classified in class 530, subclass 300.
- 33. Claim 16, drawn to a method of screening for compounds that modulates the activity of murine particle protein gene 57, classified in class 435, subclass 7.1.
- 34. Claims 17-22, drawn to a methods of screening for compounds that modulate the activity of an isolated human particle protein, classified in class 435, subclass 7.1.

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35. Claims 23-25, drawn to a methods of screening for compounds that restore activity of a defective or absent human particle, classified in class 435, subclass 7.1.

- 36. Claims 26-27, drawn to a methods of diagnosing a disorder caused by a defective or absent human particle protein, classified in class 435, subclass 7.94.
- 37. Claims 28-30, drawn to a methods of treating a disorder caused by a defective or absent human particle protein by administering a nucleic acid, classified in class 514, subclass 44.
- 38. Claims 31-36, drawn to a methods of treating an infection caused by a pathogen by administering to the subject an effective amount of an agent that inhibits the function of the particle protein, classified in class 424, subclass.
- 4. The inventions are distinct, each from the other because of the following reasons:
- 5. Groups 1-32 are drawn to different products. The claims of Inventions 1, 4, 7, 10, 13, 16, 19, 22, 25, 28 and 31 are drawn to different genes encoding different particle proteins, those of Inventions 2, 5, 8, 11, 14, 17, 20, 23, 26, 29 and 32 are drawn to different particle protein encoded by different genes and that of Inventions 3, 6, 9, 12, 15, 18, 21, 24, 27 and 30 to antibodies that bind the different particle proteins. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities that are derived from different genes, encode different gene products or bind the different gene products. The search for one gene or its gene product would not reveal art on the other genes. As such the genes, gene products and antibodies are distinct as claimed.

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6. Inventions 33-38 are drawn to different methods. The methods of Groups 33-38 rely on patentably distinct genes or gene products as discussed in above, have different method steps and have different goals as evidenced by the preambles of the methods. As such, the methods are distinct each from the other.

- 7. Inventions (3, 6, 9, 12, 15, 18, 21, 24, 27 or 30) and (36 or 38) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody could be used to purify the polypeptide or administered as an imaging agent.
- 8. Inventions (2, 5, 8, 11, 14, 17, 20, 23, 26, 29 or 32) and (33, 34 or 35) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in materially different methods of using that product such as in a method of treatment, a method of making an antibody or a method of detecting binding sites or as an imaging agent in an in vivo method of imaging. As such, the product is distinct from each of the methods.
- 9. Inventions (1, 4, 7, 10, 13, 16, 19, 22, 25, 28 or 31) and (37) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

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materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used in materially different methods of using that product such as in a method of treatment, a method of making the polypeptide or in a method of detecting expression by hybridization. As such, the product is distinct from the method.

- 10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.
- 11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

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Patricia A. Duffy, Ph.D. February 11, 2003

> Patricia A. Duffy, Ph.D. Primary Examiner Group 1600